**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/72

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| **PRODUCT** | MYDAWA PANTOPRAZOLE 40 mg TABLETS | | **REF. NO: NDQD2016061209** |
| **DATE RECEIVED:** 2016-06-23 | **LABEL CLAIM:** | Each enteric coated tablet Pantoprazole Sodium 40 mg | |
| **BATCH NO.:** R4815 | **PRESENTATION:** | Yellow coloured, circular shaped, biconvex faced tablets, plain on both sides, packed in aluminium blister strips of 10 tablets and 3 such strips in a unit box. | |
| **MFG. DATE:** Oct. 2015 | **MANUFACTURER:** | THE MADRAS Pharmaceuticals. | |
| **EXP. DATE:**  Sep. 2017 | **ADDRESS:** | 137-B, Old Mahabalipuram Road, Karapakkam, Chennai - 600 096. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | ION Kenya, Landmark Plaza, Arwings Khodek, Road, P. O. Box 46986-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol .V App XII C | NMT 2 tablets deviate by more than 7.5% from the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In house method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's In house method | No tablet more than 10% | Acid Stage Average = 1% Range | **COMPLIES** |
| **Dissolution** |  |  | No tablet is less than 80% | 1 - 2% (RSD = 14.1%; n = 6) | **COMPLIES** |
| **Dissolution** |  |  |  | Buffer Stage Average = 97% Range |  |
| **Dissolution** |  |  |  | 95 - 99% (RSD = 2.1% ; n = 6) |  |
| **Assay** | HPLC | Manufacturer's In house method | 90.0-110.0% | 93.9% (RSD = 0.5% ; n = 9) | **COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the test performed.

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| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 30/08/2016 |
| **REVIEWER** | DR. E. MBAE | .......................................................... | DATE: 30/08/2016 |
| **DIRECTOR** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 30/08/2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-05-2016 |